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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,809	07/21/2003	S. Ananth Karumanchi	01948/088004	6646

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,809	KARUMANCHI ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-40 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 13-22, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF polypeptide in a sample, wherein said subject is a non-pregnant human, classified in class 435, subclass 7.1.

II. Claims 1-10, 13-21, 23, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF polypeptide in a sample, wherein said subject is a pregnant human, classified in class 435, subclass 7.1.

III. Claims 1-10, 13-21, 24, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF polypeptide in a sample, wherein said subject is a post-partum human, classified in class 435, subclass 7.1.

IV. Claims 1-10, 13-21, 25-27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF polypeptide in a sample, wherein said subject is a non-human animal, classified in class 435, subclass 7.1.

V. Claims 11, 13-22, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF nucleic acid molecule in a sample, wherein said subject is a non-pregnant human, classified in class 435, subclass 6.

VI. Claims 11, 13-21, 23, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-

1, VEGF or PIGF nucleic acid molecule in a sample, wherein said subject is a pregnant human, classified in class 435, subclass 6.

VII. Claims 11, 13-21, 24, 27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF nucleic acid molecule in a sample, wherein said subject is a post-partum human, classified in class 435, subclass 6.

VIII. Claims 11, 13-21, 25-27, 28, 29-31 in part, and 32, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by measuring the level of sFlt-1, VEGF or PIGF nucleic acid molecule in a sample, wherein said subject is a non-human animal, classified in class 435, subclass 6.

IX. Claims 12-22, 27, 28, 29-31 in part, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by determining the nucleic acid sequence alteration of a sFlt-1, VEGF or PIGF gene in a sample, wherein said subject is a non-pregnant human, classification depending upon the method steps.

X. Claims 12-21, 23, 27, 28, 29-31 in part, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by determining the nucleic acid sequence alteration of a sFlt-1, VEGF or PIGF gene in a sample, wherein said subject is a pregnant human, classification depending upon the method steps.

XI. Claims 12-21, 24, 27, 28, 29-31 in part, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by determining the nucleic acid sequence alteration of a sFlt-1, VEGF or PIGF gene in a sample, wherein said subject is a post-partum human, classification depending upon the method steps.

XII. Claims 12-21, 25-27, 28, 29-31 in part, drawn to a method of diagnosing pre-eclampsia or eclampsia in a subject by determining the nucleic acid sequence alteration of a sFlt-1, VEGF or PIGF gene in a sample, wherein said subject is a non-human animal, classification depending upon the method steps.

XIII. Claims 33, 34 and 37-40, drawn to a kit comprising a nucleic acid of sFlt-1, PIGF, or VEGF, classified in class 435, subclass 6.

XIV. Claims 35-40, drawn to a kit comprising a means of detecting sFlt-1, PIGF, or VEGF polypeptide, classified in class 435, subclass 975.

The inventions are distinct, each from the other because:

Although Inventions I-IV are drawn to a method of diagnosing pre-eclampsia or eclampsia by measuring the level of sFlt-1, VEGF or PIGF polypeptide, they are distinct each from each other because each group involves a distinct patient population with distinct physiological and/or pathological conditions, requiring different therapy, and having distinct features in prognosis. Therefore, each group requires a separate search of the prior art.

Although Inventions V-VIII are drawn to a method of diagnosing pre-eclampsia or eclampsia by measuring the level of sFlt-1, VEGF or PIGF nucleic acid molecule, they are distinct each from each other because each group involves a distinct patient population with distinct physiological and/or pathological conditions, requiring different therapy, and having distinct features in prognosis. Therefore, each group requires a separate search of the prior art.

Although Inventions XI-XII are drawn to a method of diagnosing pre-eclampsia or eclampsia by determining the nucleic acid sequence of a sFlt-1, VEGF or PIGF gene they are distinct each from each other because each group involves a distinct patient population with distinct physiological and/or pathological conditions, requiring different therapy, and having distinct features in prognosis. Therefore, each group requires a separate search of the prior art.

Inventions I-IV are distinct from Inventions V-XII, wherein the method of I-IV is drawn to a method of diagnosis by measuring the level of the polypeptide, whereas the methods of Inventions V-XII are drawn to a method of diagnosis by measuring the nucleic acid. They involve testing different molecules, active ingredients, method steps, and outcomes. Therefore, non-coextensive searches are required.

Inventions V-VIII are distinct from Inventions IX-XII, wherein the method of V-VIII is drawn to a method of diagnosis by measuring the level of the nucleic acid, whereas the method of Inventions IX-XII is drawn to a method of diagnosis by determining the nucleic acid sequence alteration. They are methods involving distinct steps, and require different active ingredients. Therefore, non-coextensive searches are required.

Inventions I-IV are distinct from and unrelated to invention XIII, wherein the nucleic acid of Invention XIII can be neither made by nor used in the method of Invention I-IV, and wherein each does not require the other.

Invention XIV and Inventions I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit as claimed may be used for the purification of said polypeptide, or for detecting said polypeptide for different purpose other than diagnosing pre-eclampsia or eclampsia, such as in different conditions.

Invention XIII and Inventions V-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of the kit as claimed may be used for the recombinant production of the polypeptide.

Inventions V-XII are distinct from and unrelated to invention XIV, wherein the kit for detecting the polypeptide in Invention XIV can be neither made by nor used in the methods of Inventions V-XII, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

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AU1646
2/16/06